



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0788]

Pilot Program for Early Feasibility Study Investigational Device Exemption

Applications; Termination of Acceptance of Nominations and Extending the Duration of the Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the termination of the acceptance of nominations for the Early Feasibility Study Investigational Device Exemption (IDE) Applications pilot program. This program allowed the submission of nominations from sponsors of innovative device technologies to participate in a pilot program for early feasibility study IDE applications. FDA is also announcing that the duration of the pilot program is extended to May 8, 2013, for sponsors that have already been accepted for the program.

DATES: This notice is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

In the Federal Register of November 10, 2011 (76 FR 70150), FDA announced the availability of a draft guidance entitled “Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies.” This guidance document is intended to facilitate early feasibility studies of medical devices, using appropriate risk mitigation strategies, under the IDE requirements. Simultaneous with the publication of the draft guidance, FDA also announced an Early Feasibility Study IDE Pilot Program (76 FR 70152, November 10, 2011) intended to collect information and experience on the application of the draft guidance in order to inform the final guidance document.

FDA began accepting nominations for the pilot program on December 12, 2011. In the Federal Register notice announcing the pilot program, FDA stated its intention to limit the pilot program to nine candidates. After review of the nominations received in response to the pilot program notice, FDA accepted nine appropriate candidates for the pilot program.

In the pilot program notice, FDA stated its intention to accept nominations to participate in the pilot program until May 8, 2012. Because FDA has already accepted nine sponsors to participate in the program, FDA will no longer accept nominations to participate in the program and will conduct the pilot program for the nine sponsors that have already been accepted.

In the pilot program notice, FDA also stated that the pilot program will terminate on May 8, 2012. Instead, the pilot program will be extended for the nine accepted sponsors until May 8, 2013.

Dated: February 28, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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